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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/232,290	01/15/1999	ANDREAS PLUCKTHUN	MORPHO/7	1987

26633 7590 11/19/2002

HELLER EHRMAN WHITE & MCAULIFFE LLP
1666 K STREET, NW
SUITE 300
WASHINGTON, DC 20006

[REDACTED] EXAMINER

DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 11/19/2002

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/232,290	PLUCKTHUN ET AL.	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 8-29-02.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5,7-27,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,7-11,13-27,37 and 38 is/are rejected.
- 7) Claim(s) 12 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-29-02 (Paper No. 28) has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

MAINTAINED Claims 1-5, 7-11, 13-17, and 26-27 stand rejected and newly added claims 37-38, are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson et al (WO 92/01787)(IDS).

Response to Arguments

Applicant traverses the rejection. Applicant states that Johnson does not teach a DNA sequence encoding a domain of an antibody that contains a modification of an interdomain interface of the antibody as required by the instant claims. Applicant states that Johnson teaches modification of amino acid residues that would form the hydrophobic interface between the single chain variable domain and a complementary heavy or light chain variable domain. Applicant further states that the instant invention is directed to DNA sequences encoding domains having modified residues in the “inter-domain” interface, rather than on the interface between a heavy and a light chain variable region pair. Applicant contends that it is “apparent” from the instant specification that an inter-domain interface exists within a single VL/C chain or a single VH/CH1 chain. However this apparent limitation on the interpretation of the phrase “inter-domain interface” is not recited in the instant claims.

Therefore, while the examiner acknowledges the distinctness of the two types of interfaces, by reciting the phrase “inter-domain interface”, the instant claims do not exclude an inter-domain interface between the heavy and light variable regions in certain recombinant antibody molecules such single chain antibodies.

Applicant contends that new claims 37 and 38 require the presence of both a variable heavy and a variable light chain domain, and that Johnson teaches only a single variable domain and therefore cannot anticipate these claims. However, the examiner notes that Johnson teaches on page 15 alterations to frameworks that enable the generation of antibodies as well as single

Art Unit: 1644

variable domains with improved properties for in vivo use and in vitro use. Johnson further teaches on page 13 that antibodies include the immunoglobulin isotypes and Fab, scFv, Fv, dAb and Fd fragments. Therefore Johnson reads on said new claims.

Therefore, though applicant's arguments have been carefully considered, they are not persuasive and the rejection is maintained, essentially for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

MAINTAINED Claims 1-5, 7, 10-11, 13-27 and newly added claims 37-38, stand rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (WO 92/01787)(IDS) in view of Jenkins et al (PNAS 92:6057-6061, 1995)(IDS) and Knappik et al (Biotechniques 17(4):754-761, 1994) and Dubel et al. (J. Of Immunological Methods 178:201-209, 1995) and Kostelny et al (Journal of Immunology 148:1547-1553, 1992).

Applicant traverses the rejection on the grounds that Johnson does not teach a DNA sequence encoding a domain of an antibody that contains a modification of an interdomain interface of the antibody as required by the instant claims. However, as discussed above, the instant claims do not exclude an inter-domain interface between the heavy and light variable regions as taught by Johnson. Therefore, though applicant's arguments have been carefully considered, they are not persuasive and the rejection is maintained, essentially for the reasons of record.

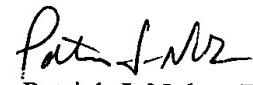
MAINTAINED Claim12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner,
November 14, 2002



Patrick J. Nolan, Ph.D.,
Primary Patent Examiner,
Group 1640